

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The Effect Of Narrative Writing On stress level Among patients families Of Intensive Care Units

Protocol summary

Summary

The aim of this research is study the effect of narrative writing on stress among patients families of intensive care units of Babol University of Medical Sciences. This is a single blinded clinical trail with before and after groups. One hundred and six patients families of intensive care unites of teaching hospitals affiliated to Babol University of Medical Services will participate in the study. Inclusion criteria are at least Age between 18- 65, At least secondary education, Absence of any other patient with a history of hospitalization in the intensive care unit, Absence of critically ill patients at home, Absence of acute stress problem in the last six months, Non-use of drugs associated with psychotic disorders in the past six months. The patients families will invite to attend in a orientation meeting to be informed about the process of research work. The intervention group will asked to write narrative one week. The data will collected with Depression Anxiety and Stress Scales (DASS-21) questionnaire before and after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016102930570N1**

Registration date: **2017-01-27, 1395/11/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-01-27, 1395/11/08

Registrant information

Name

Hosein Bagherzadeh Sheshpol

Name of organization / entity

Golestan University of Merdical Science

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Deputy of Research & Technology, Golestan University of Medical Sciences

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2016-11-21, 1395/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect Of Narrative Writing On stress level Among patients families Of Intensive Care Units

Public title

The effect of narrative writing on hospitalized patients families stress in Intensive Care Units

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria :Age between 18- 65, At least secondary education, Absence of any other patient with a history of hospitalization in the intensive care unit, Absence of critically ill patients at home, Absence of acute stress problem in the last six months, Non-use of drugs associated with psychotic disorders in the past six months. exclusion criteria :Death of patient, Acute stress

problems during the study

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **106**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethical Committee Golestan University of Medical Sciences

Street address
Golestan University of Medical Sciences ,Shastkola

City
Gorgan

Postal code
4934174515

Approval date
2016-03-09, 1394/12/19

Ethics committee reference number
IR.GOUMS.REC.1394.348

Health conditions studied

1

Description of health condition studied
Stress

ICD-10 code
F43.1

ICD-10 code description
Post-traumatic stress disorder

Primary outcomes

1

Description
Stress

Timepoint
A week

Method of measurement
DASS questionnaire

Secondary outcomes

1

Description
Anxiety and Depression

Timepoint
A week

Method of measurement
DASS questionnaire

Intervention groups

1

Description
Intervention group: The participants will asked to write at least once a clinical narrative. They will receive a notebook which is designed for this purpose. They should write about their emotions, thoughts , the worse ethical experiences, the hard moments, the bad behaviors, clinical decisions.

Category
Rehabilitation

2

Description
Control group:Stress questionnaire completed by the participants on the first day and then again after one week .

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
SHahid Yahyanejad Teaching Hospital Babol
University of Medical Sciences

Full name of responsible person
Hossein BagherZadeh

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2

Recruitment center
Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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University of Medical Sciences

Full name of responsible person

Dr Masood Khoshnya

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Deputy of Research & Technology, Golestan
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Grant name

313863/348

Grant code / Reference number

456456

**Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Deputy of Research & Technology, Golestan University of
Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Golestan University of Medical Sciences

Full name of responsible person

Hosein Bagherzadeh Sheshpol

Position

Ms Student of Critical Nursing Care

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Nursing Research Center, Golestan University of
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Full name of responsible person

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty